Section 1

510(k) Summary of Safety and Effectiveness

OCT 2 8 2010

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

Submitter:

Edan Instruments, Inc

3/F - B, Nanshan Medical

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518067 P.R. China Tel: 86-755-26882220 Fax:86-755-26882223

Contact person: Yue Qiuhong

Official correspondent:

William Stern

Multigon Industries, Inc.

1 Odell Plaza

Yonkers, N.Y. 10701 Phone: 914 376 5200 X27 Fax: 914 376 6111

Date of Preparation:

2010-7-20

Proprietary Name:

Ultrasonic TableTop Doppler (Models SD5, SD6)

Classification Name:

21 CFR 884.2660 Fetal ultrasonic monitor and accessories

21 CFR 884.2660 Ultrasound Blood Flow Monitor

Product code:

MAA/JAF

Predicate Devices:

| Predicate devices | IMEXDOP CT+ | Sonotrax series pocket Doppler | Ultrasonic TableTop Doppler |
|-------------------|------------------------------|--------------------------------|--------------------------------|
| Manufacturer | Imex Medical Systems, Inc | Edan Instruments, Inc | Edan Instruments, Inc |
| K # | K942441 | K080087 | K092997 |

Device Description:

Ultrasonic TableTop Doppler provides the following primary features:

- Basic parameters: FHR, blood flow
- 240 seconds fetal heart sound record and playback
- Infrared communication(for SD6 only)
- Ni-MH battery for 20 hours continuous working of main unit
- Li-ion battery for 2.5 hours continuous working of SD6 probe

DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration 10903 New Hampshire Avenue Document Mail Center - WO66-G609 Silver Spring, MD 20993-0002

Ms. Yue Qiuhong Certification Engineer Edan Instruments, Inc. 3/F – B, Nanshan Medical Equipment Park Shenzhen, Guangdong 518067 CHINA

OCT 2 8 2010

Re: K102138

Trade/Device Name: Ultrasonic TableTop Doppler (models SD5 and SD6)

Regulation Number: 21 CFR 884.2660

Regulation Name: Fetal ultrasonic monitor and accessories

Regulatory Class: II

Product Code: MAA and JAF Dated: September 29, 2010 Received: October 4, 2010

Dear Ms. Qiuhong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Ultrasonic TableTop Doppler (models SD5 and SD6), as described in your premarket notification:

Transducer Model Number

5MHz CW Vascular Probe-model: SD5

4MHz CW vascular probe-model SD5

8MHz CW vascular probe-model SD5

5MHz CW wireless vascular probe-model: SD6

4MHz CW wireless vascular probe-model: SD6

8MHz CW wireless vascular probe-model SD6

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Jana Delfino at (301) 796-6503.

Sincerely yours,

David G. Brown, Ph.D.

Acting Director

Division of Radiological Devices
Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)

Ultrasonic TableTop Doppler Traditional 510K Submission

Section

Indication for Use

510(k) Number (if known):

OCT 2 8 2010

Device Name: Ultrasonic TableTop Doppler (models SD5 and SD6)

The Ultrasonic TableTop Doppler is intended to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physician assistants, by prescription from licensed physicians in hospitals, clinics and private offices.

The 2 MHz and/or 3 MHz probes are indicated for the detection of fetal heart rate from early gestation thru delivery and as a general indication of fetal well being. They can also be used to verify fetal heart viability following patient trauma.

The 4 MHz, 5 MHz and/or 8 MHz vascular probes are indicated for the detection of blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or Over the Counter Use

(21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

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Diagnostic Ultrasound indications for Use Form Fill out one form for each ultrasound system and each transducer. 5MHz GW vascular probe model: SD5 Intended use: Diagnostic ultrasound maging or fluid flow analysis of the human body as follows.

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Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

4MHz.CW vascular probe-model: SD5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

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N=new indication; P=previously/cleared by FDA; e=ADDED UNDER appendix E

Additional Comments: The above is a 4MHz CW transducer for the blood flow detection.

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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Diagnostic Ultrasound indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

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Diagnostic Ultrasound indications for Use Korm

Fill out one form for each ultrasound system and each transducer. 5MHz CW wireless vascular probe-model: SD6

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Office of In Vitro Diagnostic Device Evaluation and Safety

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Diagnostic Ultrasound indications for Use Form

Fill out one form for each ultrasound system and each transducer. 4MHz CW wireless vascular probe-model: SD6

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Intended, use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

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Diagnostic Ultrasound indications for Use Form

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